Message

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To: Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]
Subject: RE: IRIS Handbook

Thanks. Ex. 5 Deliberative Process (DP)

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David D. Dunlap
O – Ex. 6 Personal Privacy (PP)

From: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Sent: Monday, September 9, 2019 8:27 AM
To: Dunlap, David <dunlap.david@epa.gov>
Subject: IRIS Handbook

FYSA

Despite GOP Calls, EPA Delays IRIS Handbook Amid Fight Over TSCA Method

September 05, 2019

Despite calls from GOP lawmakers and the National Academy of Sciences (NAS), EPA appears to have buried the handbook describing how its Integrated Risk Information System (IRIS) program conducts its risk analyses as officials in the research and toxics offices battle over a key assessment method and a system for characterizing non-cancer risks.

An April 2019 version of the handbook, obtained exclusively by *Inside EPA*, describes the IRIS program's approach to conducting its assessments, including its method for conducting systematic reviews -- a nascent approach for gathering and evaluating scientific evidence to increase the rigor and transparency of chemical evaluations -- as well as a new system for describing non-cancer risks.

But one informed source says the IRIS handbook has not been released in part because of concern from top officials in the Office of Chemical Safety and Pollution Prevention (OCSPP) who fear that the systematic review approach in the handbook differs from methods they are developing to implement the revised Toxics Substances Control Act (TSCA).

One concern is that the IRIS handbook is "not consistent with their methodology that they're using" in the TSCA program, the source says.

"It never got released because there was a lot of discussion between OCSPP and [the Office of Research and Development (ORD), which oversees IRIS] and it wasn't apparent how that would get resolved," the source says. "People heard [the handbook] was dead, but ORD is using it -- but they don't make it public."

Another informed source says the person that raised "the biggest concern" with the handbook was Nancy Beck, the former chemical industry lobbyist and long-time IRIS critic who served as President Donald Trump's first appointee to EPA's toxics office. But even after Beck's departure for a detail to the White House, the handbook remains in limbo, the source says, explaining that now another toxics official has concerns.

"Nothing has happened other than internal meetings," the source says.

This second source sees the IRIS handbook as emblematic of the administration's efforts to disband the IRIS program. "They still have this program they don't like," the source says. "They've tried every conceivable angle [to kill it] but they haven't determined how to get rid of it." And with Democrats controlling the House, they are unlikely to be able to do so, the source adds.

An EPA spokesperson said the IRIS Handbook is currently under agency review. "The IRIS webpage will be updated when additional information is available," the spokesperson said. Agency staff began crafting the handbook in response to a 2011 recommendation from NAS.

In 2016, IRIS' then-Director Ken Olden described the handbook as awaiting publication when he announced his retirement from EPA. "We've developed a standard operating procedure; it's described in the draft handbook. I had hoped that it would be released before I retired, but that is unlikely," Olden said. "It's an outstanding handbook, as I think you'll agree when you get to read it."

While a completed version of the handbook has yet to undergo peer review, draft versions were considered by NAS committees reviewing IRIS' progress in 2014 and 2018.

Systematic Review

Stakeholders and members of Congress have pressed the agency repeatedly to release the IRIS handbook, a guidance document for IRIS staff intended to describe how to perform the assessments. Last March, Republicans on the House science committee pressed for the document's release, which EPA promised to publish last year but has yet to do.

Under questions from Rep. Ralph Norman (R-SC), ranking member of the committee's oversight panel, Jennifer Orme-Zavaleta, the acting ORD chief, said March 27 the handbook is undergoing internal review at EPA, though she said "elements" of the handbook are already being captured in some of EPA's systematic review protocols.

Orme-Zavaleta said ORD had taken internal comment on the document through last December and was working to address them but some of the concerns raised were difficult. She described these issues as relating to "how we evaluate hazard, how we categorize areas of hazard. These are areas that involve more than one [EPA] office," she said, adding that she is trying to engage the agency-wide Risk Assessment Forum on these issues. "My hope is to complete this soon. I've raised it with the administrator."

One issue that appears to be holding up the document is its approach for conducting systematic reviews, an approach that NAS had urged the program to adopt in its 2011 report, and subsequent reports on the IRIS program, in order to provide a transparent way to search scientific literature and organize the information to answer questions.

EPA also states in its risk evaluation rule, one of the framework rules for implementing Congress' 2016 reform of TSCA, that it will use systematic review when performing risk evaluations under TSCA. But the TSCA program's systematic review approach has faced strong criticism.

For example, academics and environmentalists have questioned the scoring approach the toxics office used to remove some studies from consideration in the draft chemical assessments, charging it mirrors other agency efforts to block the use of scientific studies that could drive stricter regulatory requirements.

"The TSCA method's arbitrary, unscientific scoring and exclusion of studies is right in line with other attempts to restrict the science EPA relies on, such as the recent 'censored science' proposal from former Administrator [Scott] Pruitt," researchers at the University of California San Francisco wrote last year.

And Democratic lawmakers last year won a commitment from EPA Administrator Andrew Wheeler -- to secure the confirmation of toxics office chief Alex Dunn -- that the TSCA program's systematic review approach would be subject to NAS review.

While EPA science advisors recently backed EPA's development of a unique systematic review approach for TSCA, they nevertheless sought an explanation for why toxics staff developed its own approach and urged officials to ensure NAS quickly assesses it. However, EPA officials told the advisors that the NAS review may not occur until after the agency completes at least some of the first group of 10 chemicals it is reviewing, adding that they plan to provide the NAS panel with examples of how they used and applied the approach.

Non-Cancer Characterization

The sources also identified another source of tension between the IRIS and TSCA programs -- the handbook's inclusion of a weight of evidence characterization, or a descriptor, for non-cancer health effects associated with exposure to the chemical under assessment.

EPA's IRIS assessments, like assessments from other agencies, such as the International Agency for Research on Cancer or the National Toxicology Program, have long provided labels describing the evidence linking a chemical to cancer potential, describing a chemical as a "human carcinogen" or "likely to be carcinogenic to humans" or other findings based on a classification system specific to the scientific studies available.

In response to calls from the NAS, IRIS has crafted a similar system to label non-cancer risks.

The non-cancer descriptors were a feature of the IRIS handbook three years ago, when Olden said at a public meeting he did not expect the handbook to be published until after his July 2016 retirement. At the time, he said the handbook "describes how we do systematic review," and also includes new "descriptors of non-cancer hazards."

The IRIS handbook includes a chapter on "overall evidence integration conclusions" after systematic review. "Based on the integration across lines of evidence, this stage culminates in an evidence integration narrative … that summarizes the conclusions regarding each potential health effect (i.e., each noncancer health effect and specific type of cancer, or broader grouping of related outcomes …)."

The chapter notes that EPA should continue to use the cancer descriptor as outlined in the agency's 2005 guidelines on cancer risk assessment, and includes a table indicating what appear to be descriptors that could be used for non-cancer effects, described as "Evidence integration conclusion levels" ranging from "Evidence demonstrates" to "Evidence inadequate" and "Strong evidence supports no effect." --

Maria Hegstad (mhegstad@iwpnews.com)